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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,791	08/05/2002	Piet Herdewijn	0702-020249	9473

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EXAMINER	
BERCH, MARK L	

ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 09/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/070,791	HERDEWIJN ET AL.	
	Examiner	Art Unit	
	Mark L. Berch	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39,41,43 and 44* is/are pending in the application.

4a) Of the above claim(s) *8,9,10-11,13 and 24-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,12,15-23,35-39,41,43 and 44* is/are rejected.

7)☒ Claim(s) *14* is/are objected to.

8)☒ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *3/8/2002* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

Election/Restrictions

The petition decision of 6/2/2005 is noted; the petition was denied. Hence, claims 1-7, 12, 14-23, 35-39, 41 and 43-45 continue to be objected to as having non-elected subject matter present. This material must be removed. Limitation to the adenines, which is what has been examined, will resolve the matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejections over Maurinsh, et al. and Konkel, et al. are overcome by removal of X = H subject matter.

The rejections over Gannett et al, and Hiramoto have been overcome by the limitation to a single double bond in the carbocyclic ring.

Claims 1-7, 10, 12, 14-23, 35-39, 41, 43-45 are rejected under 35 U.S.C. 102(a) as being anticipated by Wang (2000) or Wang (1999).

The references were published before the filing of the PCT application, and inventorship is different from authorship, but the same subject matter is disclosed. The rejected claims are not entitled to benefit of any of the US provisional applications. None of

these applications have the scope of genus as seen in the rejected claims. A great deal of material was added to the PCT application which was not in any given US provisional application.

The traverse is unpersuasive. Applicants conceded that the rejected claims are broader than the provisional applications, but say instead that the references are "nearly identical" to these provisional applications. This argument has no legal merit. It would not matter if the prior art reference were all within the scope of the priority applications. The priority date for claims is determined without reference to the contents of the prior art reference. Once the claims have been determined to lack benefit, they are properly rejected, even though the reference contains no more than the priority application. Attention is drawn to *In re Schreiber*, 199 USPQ 782, which had this exact situation. Note also *In re Albrecht*, 168 USPQ 293.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 12, 15-23, 35-39, 41, 43-44 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Claim 15 is missing something. The new claim language says "reacting" XII, but reacting it with what?
2. What does "related viruses" in claims 41 and 43 refer to? Which families are considered related? Does this term include Iridoviridae? Polydnaviridae? Polyomaviridae? Papillomaviridae? Adenoviridae? Ascoviridae? Baculoviridae? Nimaviridae? Asfarviridae? It is noted that Herpes and Pox viruses are both DNA viruses families. Does "related viruses" perhaps mean all DNA viruses?
3. The multiple ranges for alkyl are of unknown purpose. Which one is it that defines the claims. If it is the first, then what function do the other members of the markush group perform?
4. The "wherein R1 and R2 is a protecting group" does not make sense. Presumably what is intended is "wherein R1 and R2 are combined to form a protecting group", judging from the dependency of claim 18 on claim 15.
5. The last claim 12 choice is clearly in error. The protecting group has to be monovalent as it is attached to an oxygen; this group is divalent. The traverse is unpersuasive. Applicants point to the Phenyl-C< present in e.g. compound 8 of the specification, which is a different group. That group has two single bonds, whereas what appears in the claim has a double bond, and is suitable only for protecting an amine. Second, such a group is a group which protects two oxygens at once. However, claim 1 does not provide for that. That is, it does not set forth an option wherein R1 and R2 are combined into a single moiety.

6. What would an "analogue" cover in claim 19. The traverse is unpersuasive. Applicants state that it "may be dialkyl analogues, such as benzaldehyde dialkyl acetal." How is that an analogue? It's a protected version.
7. Does Me in claim 20 stand for metal or methyl? Either is conventional. For whichever choice is made, applicants must show that one of ordinary skill in the art would have known that this choice, and not another, was intended. Likewise claim 23. The traverse is unpersuasive. Applicants insist that it is methyl, but Me is used for both purposes.

Claim 20 is rejected under 35 U.S.C. 112, paragraphs 1 and 2, as the claimed invention is not described, or is not described in such full, clear, and exact terms as to enable any person skilled in the art to make and use the same, and/or failing to particularly point out and distinctly claim the subject matter which applicant regards as his invention. Specifically:

This reaction is impossible. Thus, it is either written wrongly (paragraph 2) or if written correctly, is not enabled (paragraph 1). A reductive process will not remove the alkyl or alkenyl from the alkoxy or alkenyloxy of XVB. In fact, cleavage of such a group requires a reagent such as concentrated HBr, which will add to the ring double bond and hence would be unsuitable.

Second, the examiner cannot locate this reaction in the specification, and hence is lacks description in the specification ((paragraph 1)).

The traverse is unpersuasive. Applicants point to the page 32 reaction. That, however, does not show the cleavage of an alkyl or alkenyl from the alkoxy or alkenyloxy (cleavage of ether), but rather shows the cleavage of a an acetyl group from an acetoxy (cleavage of ester). Such a cleavage is quite conventional and can even be done by

hydrolytic agents. Cleavage of an ether to an OH requires, as stated above, a reagents such as HBr.

Second, page 32 does not constitute a description of this reaction. Page 32 is just $LiAlH_4$; it does not say reduction in general. Second, it does not teach that XVB will undergo such a reaction.

Claims 15-17, 20-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Assuming that "wherein R1 and R2 is a protecting group" intends to be "wherein R1 and R2 are combined to form a protecting group", such claim language lacks description in the specification. XIII in claim 18 is an example of such a combined protecting group, but the specification does not teach the generic concept of any such protecting group which protects two oxygens simultaneously.

Claim 41 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for herpes viruses, does not reasonably provide enablement for pox viruses generally or "related viruses". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Poxviruses are very large viruses about the size of small bacteria. They have a complex internal structure - a large double-stranded DNA genome (about 200 kbp in size) is enclosed within a "core" that is flanked by 2 "lateral bodies". The scope of pox viruses is

quite extensive, in part because there are so many genera, many of which have numerous species present. The Orthopoxvirus genus includes Camelpox, Cowpox, Ectromelia virus, Mousepox, Taterapox, Vaccinia virus, Buffalopox, Rabbitpox, Variola virus (smallpox), Volepox, Skunkpox, and the Uasin Gishu disease virus. The Parapoxvirus genus includes Bovine papular stomatitis virus, Orf virus, Parapoxvirus of red deer in New Zealand (PVNZ), Pseudocowpox virus (PCPV), Squirrel parapoxvirus. Auzduk disease virus, Camel contagious ecthyma virus, Chamois contagious ecthyma virus and Sealpox virus. The Avipoxvirus genus includes Canarypox, Fowlpox, Juncopox, Mynahpox, Pigeonpox, Psittacinepox, Quailpox, Sparrowpox, Starlingpox, Turkeypox, Crowpox, Peacockpox, and Penguinpox. The Capripoxvirus genus has Goatpox, Lumpy skin disease virus (LSDV) and Sheeppox. The Leporipoxvirus genus has Hare fibroma virus, Myxoma virus, Rabbit fibroma virus, Shope fibroma virus, and Squirrel fibroma virus. The Suipoxvirus genus has just Swinepox, and the Molluscipoxvirus genus has just Molluscum contagiosum virus (MOCV). The Yatapoxvirus genus has Tanapox virus and Yaba monkey tumor virus. The Entomopoxvirinae genus has Anomala cuprea entomopoxvirus, Aphodius tasmaniae entomopoxvirus, Demodema boranensis entomopoxvirus, Dermolepida albohirtum entomopoxvirus, Figulus subleavis entomopoxvirus, Geotrupes sylvaticus entomopoxvirus, Melolontha melolontha entomopoxvirus, Othnonius batesi entomopoxvirus, Phyllopertha horticola entomopoxvirus and Ips typographus entomopoxvirus. The Betaentomopoxvirus genus includes, Acrobasis zelleri entomopoxvirus 'L', Amsacta moorei entomopoxvirus 'L', Amsacta moorei entomopoxvirus 'L', Arphia conspersa entomopoxvirus 'O', Choristoneura biennis entomopoxvirus 'L', Choristoneura biennis entomopoxvirus 'L', Choristoneura conflicta entomopoxvirus 'L', Choristoneura diversuma entomopoxvirus 'L', Choristoneura

fumiferana entomopoxvirus 'L', Choristoneura fumiferana entomopoxvirus 'L', Chorizagrotis auxiliars entomopoxvirus 'L', Heliothis armigera entomopoxvirus 'L', Heliothis armigera entomopoxvirus 'L', Locusta migratoria entomopoxvirus 'O', Oedaleus senigalensis entomopoxvirus 'O', Operophtera brumata entomopoxvirus 'L', Schistocera gregaria entomopoxvirus 'O'and Pseudaletia separata entomopoxvirus 'L'. The Gammaentomopoxvirus genus includes Aedes aegypti entomopoxvirus, Camptochironomus tentans entomopoxvirus, Chironomus attenuatus entomopoxvirus, Chironomus luridus entomopoxvirus, Chironomus plumosus entomopoxvirusand Goeldichironomus haloprasimus entomopoxvirus. In addition there are numerous pox viruses which have not even been assigned to a genus, including Diachasmimorpha entomopoxvirus, Melanoplus sanguinipes entomopoxvirus 'O', California harbor seal poxvirus, Cotia virus, Dolphin poxvirus, Embu virus, Grey kangaroo poxvirus, Marmoset poxvirus, Molluscum-like poxvirus, Mule deer poxvirus (which it has been recently asserted belongs in its own genus), Nile crocodile poxvirus, Quokka poxvirus, Red kangaroo poxvirus, Salanga poxvirus, Spectacled caiman poxvirus, Vole poxvirus and the Yoka poxvirus.

Because of the great diversity of these viruses, which arises in part due to the wide range of mammals and birds that these infect, for a compound to work generally against these is contrary to present medical knowledge. Indeed, there is presently no agent which is effective against even a modest range of pox viruses. Currently, the only marketed antiviral that has inhibitory effects on any poxvirus is cidofovir, which, however, as of yet has not been established as effective for the treatment of any pox disease.

As noted above in point 2, there is no way of knowing what the scope of "related viruses" is.

Under such circumstances, it is proper for the PTO to require evidence that such an unprecedented feat has actually been accomplished, *In re Ferens*, 163 USPQ 609. No such evidence has been presented in this case. The failure of skilled scientists to achieve a goal is substantial evidence that achieving such a goal is beyond the skill of practitioners in that art, *Genentech vs Novo Nordisk*, 42 USPQ2nd 1001, 1006. When operativeness has been properly challenged, it is incumbent on applicant to limit the claims accordingly, cf. *In re Harwood*, 156 USPQ 673, *In re Cook*, 169 USPQ 298, I*n re Langer*, 183 USPQ 288, *In re Corkill*, 226 USPQ 1005, 1009, and *In re Rainier*, 153 USPQ 802.

Claim 14 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

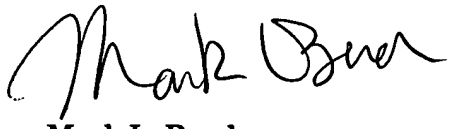
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 571-272-0663. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on (571)272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark L. Berch
Primary Examiner
Art Unit 1624

9/21/05